(Response to comment document)

OPPTS-84003A

GENERAL COMMENTS ON THE PROPOSED SECTION 8(d) RULE

Public Record Item 8.

Comment 1 Studies submitted to State agencies should be exempt from reporting.

Response EPA has not adopted this exemption. The Agency has no ready mechanism for sharing studies with the State agencies. Moreover studies submitted to State agencies are likely to have been claimed confidential and, thus, not available to EPA.

See 47 FR 38790 at 38790

Comment 2 The exemption section (§716.18(c) of the proposal) should be modified to indicate that persons are not required to list studies conducted or initiated by or for another person who is subject to this Subpart.

Response The Agency has adopted the suggestion (see §716.11(d) of the final rule).

Comment 3 Copies of studies submitted to other Federal agencies with claims of confidentiality should not be required to be submitted to EPA since this would involve duplicative reporting to the Federal Government.

Response The Agency is requiring the submission of these studies because important information may be contained in them and other agencies collect confidential business information under statutes which may not generally permit interagency data sharing.

Comment 4 Studies submitted to another Federal agency without claims of confidentiality should be exempt from listing because of interagency data sharing.

9/82

Response EPA agrees. The exemption section of the rule has been changed to exclude listing and submission of studies submitted to other Federal agencies with no claims of confidentiality, see §716.11(c).

Comment 5 EPA should evaluate the availability of results of foreign studies from existing literature search services. If such studies are not readily accessible, EPA should require the submittal of copies of foreign studies, published and unpublished, from importers and domestic companies as well.

Response EPA has adequate access to foreign, published studies. All respondents, including importers, must submit any unpublished studies in their possession, including foreign studies.

Comment 6 Persons should be exempt from reporting multi-sponsored studies if they know that the study has been submitted by another person.

Response See §716.11 which exempts companies from reporting studies already submitted to EPA.

Comment 7 Only those studies pertaining to chemical substances and mixtures containing impurities in excess of one percent should be subject to this rule provided that the manufacturer or processor has reason to believe that there is a causal connection between a demonstrated effect of a study and the presence of the impurity.

Response EPA disagrees with the commenter's rationale. No data submitted or available to EPA shows that there is a percent below which toxicity cannot be manifested. Many examples are

available which show that even very low concentrations of an impurity, such as dioxins and bis(chloromethyl) ether can manifest toxicity.

However, EPA has decided not to require submission generally of studies when a listed chemical is present in the studied material only as an impurity. If the Agency needs such studies it will propose the reporting in the FEDERAL REGISTER.

Comment 8 Clarification is needed in the preamble to the final rule to emphasize that copies are required of health and safety studies that were "conducted or initiated by or for" the parties involved. It should be more explicit that copies of studies, not "conducted or initiated by or for" the manufacturer or processor of a listed chemical, need not be submitted. Thus it would not be necessary for a manufacturer to submit copies or lists of studies which were obtained from the open literature. This would prevent a massive, duplicative submission of published data.

Response . The Agency agrees that respondents will not have to list or submit health and safety studies that the respondents obtain from open literature. However, if a respondent has a copy of a study conducted by or for someone not subject to reporting under this rule that has not been published, the respondent must submit a copy of the study.

Comment 9 It would be an intrusion by government into areas where it has no legitimate business if EPA required independent researchers to submit unpublished reports and informal communications.

Reponse EPA disagrees. Congress authorized such a requirement in section 8(d). However, independent researchers will not be required to report under this rule unless an initial respondent lists the researcher as having a copy of a particular unpublished study and the Agency requests a copy.

Comment 10 EPA exempts persons subject to the rule from submitting copies or lists of studies or data which have been published in the scientific literature. This poses two problems. First, what specifically constitutes the "scientific literature"? Secondly, literature searches would have to be carried out by virtually all persons subject to the rule in order to take advantage of this exemption.

Response The Agency does not believe it is difficult to take advantage of this exemption. Respondents should be able to tell whether a study in their possession has been published. Usually a respondent with technical expertise will know whether a study conducted by someone else was published because it is usually a reprint from a journal. If the respondent conducted the study, he should know whether it was published or not.

Scientific literature is any periodical, book or monograph which presents data obtained through a systematic pursuit of knowledge involving the recognition and formulation of a problem, the collection of data through observation and experiment, and the formulation and testing of hypotheses.

Comment 11 Under section 8(d), the inclusion of the definition for "importer" raises questions of particular significance to companies having international trading

interests. An importer is identified as a person who imports a chemical substance "including a chemical substance as a part of a mixture or article." Thus, importers are responsible for being aware of any chemical in an imported article which may be the subject of a reporting requirement. This reintroduces the issue of the status of chemical substances in imported articles addressed earlier in the inventory reporting regulations and later in the first proposed regulations for premanufacture notifications. EPA had previously indicated that it will not regard chemical substances in imported articles as subject to inventory reporting or PMN notification. To depart from these previously announced policies for the purpose of the present reporting regulations would create and even magnify the very problems which those policies properly sought to avoid. It is urged that EPA insert an appropriate explanatory notation in this rule or restate these policies.

In addition, the proposal defined importer as including any one of four different categories of individuals, i.e., consignee importer of record, actual owner, or the transferee. The ambiguity and indefiniteness of the definition complicates the situation and leads to problems in administration.

Response The Agency does have authority under TSCA over chemicals imported as part of articles. For reasons specific to the Inventory and premanufacturing notice regulations, EPA decided to exempt these importers. Generally, for purposes of those regulations, it was thought that it would be an excessive

burden for these persons to determine whether a chemical is present in the imported article.

For this rule EPA does not believe the exemption is necessary since the rule will not impose an excessive burden on the importers of articles. Most importers of articles do not have health and safety studies in their possession, nor do they normally conduct studies, so importers would have little to report. This regulation does not require importers to obtain information, but only to report on unpublished health and safety studies in their files. If they have no health and safety studies or no references to them, they do not have to report. On the other hand, if an importer does have a study such study should be submitted to the Agency under section 8(d).

EPA does not agree that the different categories of importers listed in the regulation are confusing. All can be potential importers responsible for reporting.

Comment 12 The proposed rule was not clear whether industrial hygiene studies done in plants that are under the Food and Drug Administration authority should be submitted to EPA.

Response If the respondent's entire production of a listed chemical substance is manufactured for a non-TSCA use, then the respondent is not required to report under this regulation. If all or part of his production is for a TSCA use, he must report under this regulation. EPA does not believe that he can separate industrial hygiene surveys done when he was manufacturing and processing for TSCA uses and those done when he was manufacturing and processing for food or drug uses.

Comment 13 Will EPA list procedures or tests for certain chemicals that they will accept or deem appropriate for complying with these section 8(d) rules?

Response No. The Agency does not have the authority under TSCA section 8(d) reporting rules to establish standards for testing. Testing standards and procedures will be established as appropriate by rules under section 4 of TSCA.

Comment 14 Under the section 8(d) rule, companies will be required to submit studies, for which they cannot claim confidentiality, and for which they will not be entitled to data reimbursement. Their investment in the safety of the products they manufacture, use, process, or distribute will, in effect, have been totally lost, since such studies will be in the public domain subsequent to a section 8(d) submission. The long range effect of such an inequity will be a disincentive for companies to do toxicity tests voluntarily in the future because such studies may have to be submitted without any provision for confidentiality or reimbursement. EPA should give careful thought to this problem and consider alternatives that would minimize such inequities or allow due compensation for same.

Response The Agency cannot provide compensation or blanket confidentiality for studies submitted under a section 8(d) rule. A person submitting a health and safety study may claim all or part of the study confidential. However, health and safety information about a chemical that has been offered for commercial distribution or is subject to testing under section 4 or notice under section 5 can be withheld from disclosure only to

the extent that disclosure would reveal (1) processing information and (2) percent composition of mixtures, or contains information the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), as provided in 5 U.S.C. §552(b)(6). Under TSCA, the Agency is permitted only to provide for reimbursement for studies performed under section 4 and section 5.

EPA doubts that the submitters will lose their investment in the safety of their products. It is surely a good business practice for a seller to understand any hazards involved in the use of its product.

Comment 15 Requiring reporting of monitoring data, even though the data have not been analyzed or interpreted, would inhibit initiation of independent studies funded by industry which are not strictly required by law because people may jump to conclusions on the basis of faulty or insufficient data. With the spectre of this occurring, industry might be hesitant to perform toxicological testing not strictly required by law.

Response The Agency does not believe this will be the case. Industry has conducted voluntary testing in the past because it is a good business practice. EPA believes testing will continue. Also, as previously noted, the Agency has modified the reporting requirements of the rule to only require the submission of monitoring data when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

Comment 16 There is concern throughout industry that internal industrial hygiene reports submitted under this rule will be arbitrarily passed to the Occupational Safety and Health Administration (OSHA). This would subject industry to possible self-incrimination when OSHA detects that the company exceeded limits of OSHA standards, but has not yet corrected the problem. It is suggested that this activity be specifically prohibited in the final standard.

Response While raw monitoring data might reveal technical violations of OSHA regulations, EPA does not agree that it is proper to exempt studies from reporting which might show violations of laws.

Comment 17 Requiring a company to report on studies rumored to have been conducted by third parties could lead to misinterpretation and confusion among EPA staff that the use of hearsay information often provokes.

Response EPA disagrees. The Agency is requesting "A list containing the study title and the identity and address of any person known to them to possess unpublished studies." See §716.12(a)(3). EPA believes that if a respondent has this kind of information, he has rather concrete evidence that the study does exist.

Comment 18 EPA should define the term "intermediate." Certain intermediates are completely self-contained, have zero-exposure, are very sensitive to air (O_2) and moisture and, as a result, cannot exist outside the process environment. In addition, many such chemical substances are reformulated daily,

making testing impossible. This should be kept in mind by the Agency in promulgating these regulations in order that adequate provisions can be made for this type of intermediate.

Response Persons who manufacture the listed chemicals are subject to the regulation, whether or not the chemical is an intermediate. If persons test their self-contained intermediates (which they manufacture) for health and safety reasons, then these persons are required to submit the unpublished studies if the chemical is subject to the rule. In addition, it is possible that other persons may be using the chemical in another manner.

Comment 19 A person who synthesizes or manufactures a chemical substance C from chemicals A and B as raw materials is not a processor of chemicals A and B.

Response EPA disagrees. Under TSCA section 3(10) "...[T]he term 'process' means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce -- (A)...in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture,...."

Comment 20 In the proposed rule, "copies of health and safety studies" means copies of final reports from the principal investigator. This implies that the principal investigator will be required to submit immediately to the Agency a completed toxicological study, enabling the Agency to receive the data before the sponsor. However, the term "final report" is not itself defined. The Agency should adopt the interpretation of the term "final report" as that term is used in the Good

Laboratory Practices of Nonclinical Laboratory Studies (21 CFR Part 58, as published at 43 FR 59986, December 22, 1978), in particular, 21 CFR 58.185. If the Agency feels that it must be informed within a reasonable time after a toxicological study has been completed, it could set a specified time that the sponsor would have to report the results of a toxicological study. It is the manufacturer's responsibility to report health and safety studies, not the investigator's.

Response The Agency has eliminated the definition of "copies of health and safety studies." It is the sponsor (company) of the study, not the principal investigator, who is responsible for submitting the study.

Comment 21 Several definitions in the proposed rule differ from earlier Agency definitions of the same term. To the extent a term has been defined in earlier regulations, it must remain unchanged in subsequent regulations. Introduction of multiple definitions of the same term under TSCA will guarantee confusion and unintentional noncompliance.

Response The Agency agrees that, to the extent possible, it is important to maintain common definitions. However, the Agency is not required to use the identical definition in all rules. In many cases, it is necessary to tailor a definition to the specific requirements of a given rule. To use the same definition simply because it was previously used, can be draconian and may give rise to confusion when viewed in the context of that given rule.

Comment 22 EPA should not hold the "natural person" responsible for violations of section 8(d).

Response The Agency disagrees. TSCA does not explicitly define "person," but as used in the Act the term clearly includes individuals. For example, sections 19, 20, 21, and 23 of TSCA use the term "person" in contexts that do not apply only to business entities. In enforcing this rule, EPA will take into account the considerable body of law that has developed with respect to the liability of individual employees of business entities. This body of law applies to TSCA.

Comment 23 The definition of "person" should not include "any individual" because it creates the possibility that employees of businesses covered by the rule would have an independent duty to submit reports to EPA. This is an impermissible extension of the section 8 reporting requirements, because under TSCA the term person denotes only business entities.

Response The Agency disagrees. EPA is not requiring individual employees to submit data under this rule; it is the responsibility of the company. However, individuals (persons in possession) might be required to report if a list received from a company includes a study possessed by that individual. As noted in the response to comment #22, TSCA does not explicitly define "person," but as used in the Act the term clearly includes individuals.

Comment 24 OSHA and NIOSH have developed standards and criteria documents for a number of chemical substances based on

in-depth review of the literature and health and safety studies. Chemicals covered by these standards or criteria documents should be removed from the EPA list.

Response Studies and standards published by OSHA and NIOSH or documents in the published literature are not subject to reporting under this rule. However, the chemicals covered by these standards and criteria documents may be the subject of additional study. In addition, companies may possess unpublished studies which were not available to OSHA or NIOSH. EPA is interested in having all such studies reported to it.

Comment 25 A definition of asbestos which includes "tremolite, actinolite, and anthophyllite" as asbestos is overly inclusive and would require producers of the non-asbestiform varieties of these materials to report even though the products involved actually contain no asbestos. This is an unnecessary burden and can be prevented by limiting the definition to "tremolite asbestos, actinolite asbestos and anthophyllite asbestos."

Response The Agency agrees and has changed the definition.

Comment 26 The information available to EPA and the ITC indicates the inappropriateness of including dichlorobenzidine-based pigments within the proposed rule.

Response The Agency has assessed currently available information on dichlorobenzidine-based pigments and believes that they might pose environmental or health risks. However, EPA believes that they should not be grouped with the benzidine-based dyes category because of marked differences in their metabolic

and environmental fate. Therefore, EPA is removing these pigments for further study.

Comment 27 Antimony oxide (trioxide) should not be subject to the rule. The toxicology of antimony oxide has been examined and invariably the results are being confused by EPA by the presence of arsenic and/or lead. The data indicate that when antimony oxide is pure it does not show the same effects as when it contains quantities of arsenic and lead. The commercial grade of antimony oxide being offered to the marketplace contains approximately 0.240 percent arsenic and 0.120 percent of lead. The product of that composition, representing a composite of antimony oxide samples of all U.S. manufacturers, was tested some time ago. The results of these studies were freely reported.

Response The Agency disagrees. The ITC recommended antimony trioxide for the following reasons: (1) substantial worker exposure (over 80,000); (2) approximately ninety percent is used as a flame retardant; (3) physical and chemical properties which suggest accumulation in the soil/sediment system; (4) existing inadequate tests measuring carcinogenic activity; (5) positive mutagenicity tests, and (6) possible teratogenic effects. In addition, there is an industry report showing the development of lung tumors in rats chronically exposed to antimony trioxide. To the extent there is controversy on the presence of lead or arsenic, the unpublished studies required under this rule may assist the Agency in evaluating this problem.

Comment 28 Several comments indicated that descriptions of chemicals to be encompassed by categories listed in the rule were vague. They stated that the scope of the category should be clarified to ensure proper compliance with the rule. One commenter suggested that the final rule should specifically list each CAS number encompassed by each category.

Response EPA has provided additional guidance in the list of chemicals. The list of examples of members of each category has been expanded and better category definitions are provided. However, the listed members of a category are still only examples, and respondents will have to report on other members of the category. The categories subject to the rule are groups of structurally related chemicals, not artificial groups. Respondents should not find it very difficult to identify chemicals they have dealt with within a structural category.

Comment 29 One comment interprets the proposal as applying only to those benzidine-based, o-tolidine based, o-dianisidine-based and other bisazobiphenyl dyes which are individually listed in the rule. The contention is that other unlisted members of these categories should not be covered because they are not commercially significant and would not be of practical value.

Response The Agency disagrees with this interpretion. Specific chemical substances listed under a category are only examples of members of the category and are not intended as limits on the category. EPA needs all studies done on any bisazobiphenyl dye so that it can make an accurate assessment of the entire category. Because members of the category are

structurally related, toxicology information developed on the dyes that are not commercially significant will be useful in investigating the commercially significant members of the category.

Comment 30 The use of mandatory letter requests under section 8 is unlawful. Section 8 is to be implemented exclusively by rule.

Response The Agency is implementing TSCA section 8(d) by rule. Within the rule, it now provides for voluntary letter requests to ease the burden of the rule on industry and the Agency. The Agency will use voluntary letter requests only in very specific circumstances: to request the submission of copies of specific health and safety studies that were listed in compliance with the listing requirements, and to request the underlying data for a health and safety study already submitted under the rule. If the information is not voluntarily submitted, EPA has the option of subpoenaing the information under section 11 of TSCA.

Comment 31 Submission of medical records should be subject to the approval of the patient involved. EPA should also request the medical information from both the patient and his employer. EPA should respect the normal confidential relationship between a patient and his doctor and adjust its reporting requirements accordingly.

Response The Agency will not often receive individual medical records since it considers them to be underlying data; however, when it does receive them (through voluntary requests),

it will protect the identities and other information related to the patients involved in accordance with 5 U.S.C. 552(b)(6) and will abide by all other applicable laws that protect medical records.

Comment 32 The confidentiality section is unnecessarily broad in dealing with confidentiality claims, and additional language is needed to make it more specific. As presently stated, if a company has confidential business information in a health study, it can submit a second copy with the confidential information deleted. This then becomes the copy available to the public. No review process or rejection of confidentiality is indicated in the proposed ruling. Some provision is needed to check abuse on this matter. There should be some formal review mechanism so that the EPA can review the company's exemption request, and prepare a third copy for the purpose of disclosure that would remedy any abuse while still preserving legitimate trade secrets. Furthermore, EPA should code their confidentiality exemptions so that the disclosable copy would contain appropriate markings for both process exemptions or mixture exemptions.

Response The Agency will require the respondent to state briefly the basis for confidentiality claims and will review these claims to see if they appear valid on their face in light of the categories of confidential information under section 14(b). These categories are few and well defined. If the information that the respondent claims to be confidential is not process information or mixture composition, and not relevant to

the study, or otherwise confidential under section 14(b), the Agency may challenge the claim that the information is confidential through the procedures in 40 CFR Part 2. Neither industry nor the Agency should have trouble deciding if information falls under those categories. Review of confidentiality claims would also be triggered by requests under the Freedom of Information Act.

Comment 33 EPA should provide a procedure to permit affected parties to assert claims of confidentiality or trade secrets, especially where a second or third party submitter is involved and the possibility of an infringement of copyright or breach of a secrecy and/or confidentiality agreement exists.

Response This issue was addressed in the response to CMA's petition to rescind the July 18, 1978 section 8(d) rule. The Administrator pointed out that the manufacturer, processor, or distributor of the studied chemical could have submitted the study himself. He then stated:

> However, if the company does not possess a copy of the study or does not acquire and submit a copy to EPA in response to this regulation, we reserve the right to acquire the study directly from the contractor. As a courtesy, however, to the sponsoring firm, we will contact it by phone or letter to inform the firm that we intend to obtain the study from the contractor unless the firm furnishes it to EPA within a specified number of

days. If the firm fails to do so and we contact the contractor pursuant to section 730.7 (§716.8 of this rule, now voluntary), the contractor is under an independent obligation to comply. Any person submitting a health and safety study may make a business confidentiality claim for such data under section 730.8 (§716.16 of this rule). However, if the manufacturer is concerned about preserving confidentiality, it is up to him either to submit the study himself with a claim of confidentiality or to arrange for the contractor to submit and substantiate such claims. 43 FR 56726.

Comment 34 The confidentiality protection for mixtures is too narrow. It protects only component percentages not the presence of a component. Many proprietary compositions will be subject to very damaging exposure if the components all must be named, for it is often the mere presence of a substance that is the key to successful performance. Provisions must be made to prevent disclosure of proprietary information regarding mixtures.

Response Under the specific language of section 14(b), the Agency can hold as confidential only data disclosing the confidential portion of a mixture comprised by any of the chemical substances in the mixture.

Comment 35 The confidentiality section should be clarified to permit a claim of confidentiality to apply to identification

of specific locations within a company where a study has been conducted.

Response There cannot be a blanket rule in this area. The specific location within a company where a study was conducted will be an integral part of the study if the study relates the hazards of a chemical substance to a particular activity. In other cases, location may be irrelevant. Whatever the case, the Agency will not reveal this information if identifying the location would reveal confidential business information protectable under section 14(b) of TSCA.

Comment 36 Often a company utilizing a particular chemical will receive information about the toxicity of that chemical in very summary form such as a label or safety data sheet that reflects conclusions, or presumably reflects conclusions, of studies that are not identified or cited. Would such summary information obligate a reporting company to advise the Agency of the source of the label or safety data sheet, and would there be an obligation for a reporting company to attempt to ascertain from that source whether, or what studies underlie the summary information?

Response The user company does not have to list the information about toxicity that it receives on labels or safety data sheets because the company that supplied the chemical will be required to report the source of the information on the labels and data sheets if it is unpublished data.

Comment 37 EPA should exempt small processors (to be defined as processors with annual sales of less than $250

million) from the rule on an interim basis until the Agency evaluates the information received from those not exempt.

Response The Agency disagrees. Section 8(d) does not specifically provide for exempting small businesses. Before considering whether certain persons should be exempt from reporting, the Agency must be able to evaluate the studies received during the first iterations of this section 8(d) rule. The fact that the studies were performed by small businesses in no way denigrates the value of the data. Also, the Agency believes that small companies do not possess many unpublished studies since they are less likely to be able to afford to do these studies, and therefore they would rely on the published literature and data provided by their suppliers. Therefore, the burden on small companies is expected to be very small.

Comment 38 Prior submission to EPA of final reports could impair the chances of the same material being published through the usual scientific journal outlets, which in turn could discourage the production of needed data.

Response The Agency does not believe that requiring submission of unpublished studies will impair the chances of publishing the same material. EPA does not publish the studies. However, the studies are available to the public in the OPTS Reading Room. Also, based on the Agency's earlier experience with section 8(d), EPA expects that few of the studies it receives will be intended for publication.

Comment 39 Processors should be exempt from these reporting regulations since they are unlikely to perform the type of

studies useful in determining what chemicals need further testing.

Response The Agency disagrees. Processors may have a greater concern about the health and environmental effects of a chemical substance being used in a certain way than the manufacturer of the chemical. It is a good business practice for them to know about the potential hazards of the chemical substances they are marketing, hence, they will often conduct health or environmental studies. Since these studies may be oriented to discovering the effects of a substance in its ultimate use, the Agency feels these studies are very important for it to have when making regulatory decisions on the chemical substances. Also, as stated previously, the Agency needs to examine many types of studies that, taken as a whole might indicate the need for testing, although individually they might not indicate the need for testing.

Comment 40 Two regulations, OSHA Access to Employee Exposure and Medical Records (45 FR 35212) and TSCA section 8(e), together are entirely sufficient for the Federal government to use in ensuring that previously unknown information concerning harmful effects of chemical substances is made public. The section 8(d) rule is therefore redundant, constitutes an unnecessary burden on industry, and would appear to infringe upon OSHA's responsibilities in the area of worker health. If EPA needs specific information on the effects of chemicals on worker populations, it can be obtained through OSHA channels.

Response The three regulations, OSHA Access to Employee Exposure and Medical Records, TSCA section 8(e), and this rule, complement rather than duplicate each other. The OSHA regulation merely involves recordkeeping, not reporting, and does not cover the types of studies EPA hopes to collect under this rule. TSCA section 8(e) requires reporting only if a person finds evidence of substantial risk from a chemical substance. This rule is broader in scope. EPA requires all pertinent studies on a chemical to be submitted, not just reports of substantial risk or studies of employee exposure.

This rule does not infringe upon OSHA's responsibilities for worker health. EPA's responsibilities under TSCA include, but are not limited to, worker exposure. The Agency's policy is to examine all exposures to a chemical substance in order to make an adequate assessment of it.

Comment 41 The Dyes Environmental and Toxicology Organization (DETO) urges EPA to reduce the reporting and file search burden of this proposal by exempting those studies included on the list which DETO will be supplying and all the references contained therein from either the copy submission or the listing requirement of the proposed rule.

Response Individual respondents would not have to list the studies that are on the list that DETO is submitting since persons do not have to submit list of studies that appear in a list previously submitted to EPA, see §716.11(b). They may, however, have to submit the studies on the list that are unpublished and in their possession if they know they will not be

submitted by another person. The list submitted by DETO is not a sufficient substitute for compliance with the copy submission requirements.

Comment 42 EPA stated that persons in research labs and universities are excluded from submission of studies since they "are likely to publish their findings" and "such persons who possess unpublished studies would be covered by the requirement to submit them in response to a letter if the studies are listed in accordance with §716.16 (persons in possession of listed studies)."

The latter statement is not always correct since many minor studies, papers, etc. that go unpublished are not known outside the academic community or a particular institution. To insure that a complete information and data search is achieved, it is suggested that EPA revise the submitting requirements to include research centers and universities.

Response The Agency has the authority under TSCA to subject these persons to reporting. However, we believe that our approach will produce most of the significant studies.

Comment 43 The Agency should provide some sort of "pre-rule" notification to industry so that large firms could establish the organization necessary to insure orderly and complete compliance with the rule.

Response The Agency believes that the proposal period for rules acts as pre-rule notification. In addition, the scope of this rule is less than the scope of the section 8(d) rule published in 1978. Industry has had quite a long period to

consider the steps needed to comply with section 8(d), and in fact, certain industry representatives have indicated that their companies are already formulating procedures for complying with the rule.

Comment 44 The proposed section 8(d) regulation exceeds statutory authority in that it requires submission of health and safety study lists for "new chemical substances". Section 5 of TSCA represents the sole vehicle through which EPA may obtain information on chemicals not appearing on the section 8(b) Inventory. The Agency is thus precluded from utilizing section 8(d) authority to require health and safety studies on new chemical substances.

Response Section 8 authority is not limited to "existing" chemicals. While section 5 provides a principal source of information on new chemicals, the premanufacture notifications required by that section represent neither the exclusive nor the exhaustive mechanisms through which the Administrator may gather information on new substances. However, as previously discussed EPA has exempted persons from reporting R & D studies on new chemical substances.

Comment 45 EPA must affirmatively consider the applicability of statutes other than TSCA prior to proceeding under section 8. Section 9 requires perusal and analysis of other authorities before proposing reporting requirements. Also, EPA must provide a detailed and systematic analysis of the relationship between TSCA and other applicable laws before utilizing TSCA for a particular purpose.

Response EPA disagrees. It is apparent from the wording of the Act that sections 9(a) and (b) are triggered only after an assessment of risk has been made. Section 9(a)(1) provides, in part, that "[i]f the Administrator has a reasonable basis to conclude that [certain activities] present or will present an unreasonable risk of injury...," the Administrator shall, in his discretion, determine if another Federal law could adequately prevent or reduce the perceived risk. Because section 8 rules are not dependent upon risk assessment for activation or applicability and, in fact, produce the requisite underlying data for a rational risk assessment itself, it is clear that the requirements of section 9 are wholly inapplicable to section 8 activities. Express recognition of this intended limitation on the scope of section 9 is evident from the Conference Report:

> Of course, the requirement to examine other EPA laws and to make determinations applies only when the Administrator takes regulatory action to protect against an unreasonable risk under this Act. It does not apply when the Administrator takes action necessary for the administration or enforcement of the Act, such as issuing recordkeeping requirements. H. R. Rep. No. 1679, 94th Cong. 2d Sess. 85 (1976).

Of course, as a matter of sound policy, and in accordance with section 8(d), EPA coordinates on all its chemical investigations with other appropriate Federal agencies and departments.